MAY 01 2002



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# [510(k)]
# Summary

**Submitted by:**

**Miltex Inc.**
**700 Hicksville Road**
**Bethpage, New York 11714**
**Tel: 516-349-0001**

**Contact:**

**Richard Gordon**
**RA/QA Manager**
**Tel: 516-576-6022**
**Fax: 516-576-8122**

**Signature**

November 21, 2001
**Date**

# [510(k)] Summary (Continued)

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**Common/Trade Names:** Steinmann and Fixation Pins

**Classification Names:** Pin, Fixation, Smooth
Pin, Fixation, Threaded

**Substantial Equivalence Claim:** Miltex Inc. is claiming Substantial Equivalence for our Fixation Pins, Smooth and Threaded based upon the cross referenced information as presented in the Spread Sheet, pages 5-2 and 5-3, which clearly indicates a large representation of other manufacturers. Their similar products have been utilized in the medical device market for many years. In addition, the subject Pins have already been assigned Product Codes of 87HTY and 87JDW by the FDA. The FDA in these classifications has already issued 510(k) numbers to manufacturers who sell and or distribute these product lines.

The "Statement of Intended Use" adequately describes the product functions, concepts of use and device designs related to material used for manufacture. Certificates of Mill Analysis will be maintained in our Device History Records (DHR), as evidence of the 316LVM material used to produce these products.

Miltex Inc. will assure that product will be manufactured as indicated above and with the further confirmation that the Pins will meet all parameters of our print specifications and current ISO standards referenced under Performance Standards, Miltex Inc. then hereby claims that these Steinmann/Fixation Pins are Substantially Equivalent.

The above attestation therefore deems this product as being Safe and Effective. Our (5) plus years in which Miltex Inc. has already sold Steinmann/Fixation Pins in the Veterinary marketplace, serves as additional confirmation of the Safety and Effectiveness of this new product line. Miltex Quality records for these products support our claim.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 01 2002

Mr. Richard Gordon
Regulatory Affairs/Quality Assurance Manager
Miltex, Inc.
700 Hicksville Road
Bethpage, NY 11714-3490

Re: K013888
Trade/Device Name: Pins, Fixation (Steinmann), Smooth and Threaded
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HTY, IDW
Dated: February 27, 2002
Received: February 28, 2002

Dear Mr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Miltex



**510(k) Number: K013888**

**Device Name: Pins, Fixation (Steinmann), Smooth and Threaded**

**Indications for Use:**

**1. It is the intention of Miltex Inc. to introduce into the marketplace a line of Fixation/Steinmann Pins both Smooth and Threaded.**

**2. The material is 316LVM, Stainless Steel and the Pins are to be utilized for internal fixation of bone fractures.**

**3. The Pins are used specifically for fractures of the proximal or distal end of long bones such as intracapsular intertrochanteric, intercervical, supracondylar, or condylar fractures of the femur.**

**4. The device(s) may be implanted or attached through the skin so that a pulling force (traction) may be applied to the skeletal system.**

for Mark N Milkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013888

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